## REMARKS

In the Final Office Action of December 22, 2010, claims 6, 7, 9 and 24 are pending and 6, 7, 9 and 24 are rejected.

In particular:

- Claims 6, 9 and 24 are rejected under 35 USC 103(a) as being as being unpatentable over Brightbill (US 2003/0204245) in view of Cox et al (US 5,824,040)
- Claim 7 is rejected under 35 USC 103(a) as being unpatentable over Brightbill (US2003/0204245) in view of Cox et al (US 2002/0120327) and further in view of McNamara et al (US 6,004,347).

## CLAIM AMENDMENTS

There are no claim amendments in this response

## DISCUSSION

### Response to Arguments

The Examiner has indicated in his Response to Arguments that:

"As an initial matter, it appears applicant is making arguments that have already been proven not persuasive and categorically incorrect. For example, applicant has decided to once again argue the teachings of Brightbill do not support an interpretation of a graft material covering some, but not all, of the stents. This argument was addressed in the advisory action mailed 6/1/2010. Therefore, it appears applicant is merely unnecessarily delaying prosecution by bringing back arguments that were already addressed."

With respect, however, the Examiner's opinion on a cited reference is just that, an opinion, and can be argued against. Otherwise there would be no point in responding to any Office Action. With respect, applicant is not delaying prosecution but in placing before the Examiner argument from the inventors with many years experience in actually working with and using endovascular devices.

The cited reference Brightbill has been reviewed by the inventors and it is quite apparent to them that it does not even accidentally fall within the scope of the claimed invention. It could not by itself or in combination with Cox et al be used for the purpose of the invention nor would it suggest to an non-inventive skilled person a solution which might be tried to solve the problem faced by the inventors.

To set the facts straight, Brightbill does not show a graft material covering some, but not all, of the stents. It shows some but not all of the single stent has a coating of a therapeutic material onto the struts of the stent as is discussed in Brightbill in paragraph [0023] where it is stated:

"For clarity, it must be set forth that while the coating 120 is depicted as a shaded region of the entire portion of the stent 100 (in this FIG. as well as in all the other FIGS. of this application), in the preferred embodiment the coating covers only the stent framework and does not also cover the openings or cells there between."

Brightbill does go on to say that:

"The invention may also be used on stents featuring a drug delivery vehicle in which the cells are not open, including sheath wrapped stents (such as those depicted in Froix, U.S. Pat. No. 6,019,789) as well as other delivery matrices (such as those depicted in Kaplan, U.S. Pat. No. 5,342,348). In such embodiments the sheath or other delivery matrices would be disposed on only a portion of the length of the stent."

This is not, however, a teaching or suggestion of the particular claimed construction of a covered portion and an uncovered flexible stent assembly portion.

A person skilled in the art when viewing the reference Brightbill would clearly see a single stent with portions clearly indicated as being coated with a therapeutic agent and parts which are not . It is essentially a single device, a stent. It is not an assembly of stents with flexible links between them as required for the present invention. A person skilled in the art would not go to Cox et al, another balloon expanded stent disclosure, to find links because they would not add any functionality to the purpose of Brightbill.

The Examiner has further referred us to US 6019789 (Froix et al ) which he states refers to covering stents. Figure 7A of Froix et al does show a stent wrapped in a polymer member but it certainly does not show a covered portion and a uncovered portion. Like Brightbill, Froix et al shows a single balloon expandable stent for angioplasty. It would not be suitable for treatment of aortic dissection and does not teach or suggest the limitations given in Claim 24.

The Examiner appears to be arguing that a non-inventive skilled person who was looking for a device for treatment of aortic dissection and who stumbled upon Brightbill or Froix et al would find them useful. They would not. A non-inventive

person skilled in the art would in fact discard then immediately, first, because they would not provide the continuous pressure a self expanding stent assembly would provide and second, because of their lack of flexibility. The Examiner then makes the imaginary construct that having seen their lack of usefulness the non-inventive skilled person would find Cox et al useful but we submit that this would not occur because Cox et al also does not have any or all of the characteristics needed and there is nothing in Brightbill or Froix et al to suggest where flexible links might be put because in each case a single stent is shown.

The Examiner has further stated that:

"Examiner also maintains that applicant has not shown any criticality for having 8 - 10 uncovered stents, and absent any criticality, Examiner will hold this limitation to have been obvious as set forth above and as described in detail in the non-final rejection mailed 7/7/2010 (at paragraphs 10 and 11)."

The Examiner will of course understand that there is no requirement to specifically state the advantages of the claimed invention but in fact they are abundantly clear from the specification and drawings.

An aortic dissection generally occurs high up on the descending aorta and hence that area of the device of the present invention has the proximal covered portion to close off the tear in the vessel wall. Further down, besides the major arteries illustrated in Figure 1, for instance, there are a number of intercostal arteries which branch from the aorta and then extend between the ribs to the spinal column. It is essential that these are not covered if at all possible, to avoid spinal paraplegia, so the elongate uncovered portion is essential. The length is because the length of the thoracic descending aorta is, as illustrated, quite long and there is no certainty where the possible return tear, if present, might be and if the return tear is present it should not be covered by graft material. The elongate uncovered portion may extend down to the celiac and superior mesenteric arteries and again these should not be covered by a graft material but these are not compromised by the use of the stent assembly of the present invention. In essence, therefore, a length of 8 to 10 uncovered stents linked together to provide pressure on the false lumen perhaps down as far as the celiac and superior mesenteric arteries is important. If the false lumen is not so long there is no disadvantage in having a length of 8 to 10 uncovered stents because the struts of the stents will not occlude any branch

arteries. The length is in fact an important part of the invention.

**Claim 24**

As has been discussed above the reference Brightbill does not teach or suggest a stent graft assembly with a graft material supported by self expanding stents forming a covered portion and an assembly of self expanding stents flexibly linked together forming an uncovered portion. The addition of Cox et al does not add those features not shown in Brightbill.

We submit that for these reasons Claim 24 is patentable over Brightbill (US 2003/0204245) in view of Cox et al (US 5,824,040).

**Summary**

None of the cited references Cox et al (US 5,824,040), Cox et al (US 2002/0120327), Brightbill (US 2003/0204245) and McNamara et al (US 6,004,347) whether taken singly or in any allowable combination anticipate, teach or suggest the claimed invention. We submit that Claims 6, 7 and 9 which depend from Claim 24 are inventive over Brightbill (US2003/0204245) in view of Cox et al (US 2002/0120327) and further in view of McNamara et al (US 6,004,347). Further valid argument against these references has been provided in previous responses. Overall we submit that all claims are not anticipated and are patentable over the cited references.

The re-examination and reconsideration of this application is respectfully requested and it is further requested that this application be passed to issue.

Although the foregoing discussion is believed to be dispositive of the issues in this case, applicants' attorney requests a telephone interview with the Examiner to further discuss any unresolved issues remaining after the Examiner's consideration of this response.

Respectfully submitted,

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